DETAILED ACTION

The Amendments filed on Oct. 25, 2010 has been received and entered.

Currently, Claims 1-3, 5-6, and 12-29 are pending. Claims 1-3, 5, 12-22, and 25-27 are examined on the merits. Claims 4 and 7-11 are canceled. Claims 6, 23-24 and 28-29 are withdrawn.

In view of the Appeal Brief filed on Oct. 25, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Terry A McKelvey/

Supervisory Patent Examiner, Art Unit 1655

Claim Objections

Claim 21 is objected to because of the following informalities: The word "polyoelefin" is misspelled. Appropriate correction is required.

Claim 23 is objected to because they all depend from non-elected Claim 6. If Claim 23 were cancelled, a rejection under 35 U.S.C. 112, second paragraph would be required. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 depends on the canceled Claim 8. Therefore, the metes and bounds of claim 24 are not clearly understood. Appropriate correction is required.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 22 recites the broad recitation 0.5-1.5, and the claim also recites 06-1.0 mm which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 12-17, and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Tisa-Bostedt et al. (US 2004/0001882 A1) and as evidenced by Cote et al. (US 2009/0209571 A1).

Tisa-Bostedt et al. teaches a transdermal system with fentanyl matrix patch as the active ingredient and aloe vera extract (Claim 1) with an adhesive is a styrene-butadiene-styrene block polymer (Claim 7), a polyester film as the laminating layer (claim 11). Extract of aloe vera is combined with soybean oil that are hydrogenated [0061]. Fentanyl base is dissolved in volatile solvent such as ethanol for dispersion [0062]; thus, a penetrating agent is taught. Fentanyl is a type of opioid analgesic from phenanthrene group (see Cote et al. [0052]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tavares et al. (WO 02/087482 A1) in view of Cote et al. (US 2009/0209571 A1) and Nielsen (WO 98/01167).

Tavares et al. teaches opioids, such as fentanyl matrix, as transdermal agent in a patch, backing film, adhesive, foil release liner (Abstract). Fentanyl is a type of opioid analgesic from phenanthrene group (see Cote et al. [0052]).

However, Tavares et al. does not teach styrene-butadiene-styrene block copolymer and aloe.

Nielsen teaches aloe protects skin from body execretion (page 10, lines 3-6) and use as an adhesive agent as an ostomy paste, where the patch can be made of styrene block copolymers (page 10, lines 19-20) with butadiene (page 11, lines 6-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to opioid patch with aloe because aloe protects skin from body excretions and can give the patch a better seal against the skin for a complete delivery of the opioid agent as taught by Nielsen. One would have been motivated to make opioid patch with aloe for the expected benefit of better seal for complete delivery of the active agent in a transdermal patch. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use styrene block copolymer, such as styrene-butadiene-styrene, because styrene type block copolymers are typical variance of the adhesive matrices used in practice. One would have been motivated to make block polymer with styrene-butadien-styrene for the expected benefit of forming an adhesive ostomy patch as taught by Nielsen . Absent evidence to the contrary, there would have been a

reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Claims 1-3, 5, 12-22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tavares et al. (WO 02/087482 A1), Cote et al. (US 2009/0209571 A1) and Nielsen (WO 98/01167) as applied to claims 1-3 and 5 above, and further in view of Fischer et al. (US 6455066 B1).

The teachings of Tavares et al., Cote et al., and Nielsen are set forth above and applied as before.

The combination of Tavares et al., Cote et al., and Nielsen do not specifically teach the soybean oil, polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 and especially 0.6 to 1.0 mm, penetrating agent N-methyl pyrrolidone, organic acid.

Fischer et al. teaches dermal drug for formulations and penetrating agents for transdermal administration with vegetable oil, such as hydrogenated soybean oil (column 2, lines 11-12). A patch comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents can be N-methyl pyrrolidone (column 7, lines 9, 14). Suitable preservatives include organic acids (column 6, lines 61-62).

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a patch with soybean oil, polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 and especially 0.6 to 1.0 mm, penetrating agent N-methyl pyrrolidone, organic acid because these are components are used in a patch for application to skin. One would have been motivated to make a patch for skin for the

expected benefit of increasing skin penetration and effective application on a patch formulation as taught by Fischer et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use preservatives in transdermal analgesics because preservatives such as organic acids can be used to prevent spoilage of drugs. One would have been motivated to make formulation for patch for the expected benefit of preventing spoilage of the drugs. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use buprenorphine as an analgesic because buprenorphine is an acceptable form of opioid analgesic. One would have been motivated to make formulation for patch for the expected benefit of providing local analgesic on a transdermal patch. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Claims 1-3, 5, 12-22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tisa-Bostedt et al. (US 2004/0001882 A1) in view of Fischer et al. (US 6455066 B1).

Tisa-Bostedt et al. teaches a transdermal system with fentanyl matrix patch as the active ingredient and aloe vera extract (Claim 1) with an adhesive is a styrene-butadiene-styrene block polymer (Claim 7), a polyester film as the laminating layer (claim 11). Extract of aloe vera is combined with soybean oil that are hydrogenated [0061]. Fentanyl base is dissolved in volatile solvent such as ethanol for dispersion [0062]; thus, a penetrating agent is taught. Fentanyl is a type of opioid analgesic from phenanthrene group (see Cote et al. [0052]).

Tisa-Bostedt et al. does not specifically teach polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 'and especially 0.6 to 1.0 mm', penetrating agent N-methyl pyrrolidone, organic acid.

Fischer et al. teaches dermal drug for formulations and penetrating agents for transdermal administration with vegetable oil, such as hydrogenated soybean oil (column 2, lines 11-12). A patch comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents as a N-methyl pyrrolidone

(column 7, lines 9, 14). Suitable preservatives include organic acids (column 6, lines 61-62).

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a patch with soybean oil, polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 and especially 0.6 to 1.0 mm, penetrating agent N-

methyl pyrrolidone, organic acid because these are components are used in a patch for application to skin. One would have been motivated to make a patch for skin for the expected benefit of increasing skin penetration and effective application on a patch formulation as taught by Fischer et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use preservatives in transdermal analgesics because preservatives such as organic acids can be used to prevent spoilage of drugs. One would have been motivated to make formulation for patch for the expected benefit of preventing spoilage of the drugs. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use buprenorphine as an analgesic because buprenorphine is an acceptable form of opioid analgesic. One would have been motivated to make formulation for patch for the expected benefit of providing local analgesic on a transdermal patch. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PATRICIA A LEITH/

Primary Examiner, Art Unit 1655

May 11, 2011

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Examiner Art Unit 1655